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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER | |
|---|---|
| SEHARASEYON, JEGATHEESAN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | |

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/008,721 | SAUS, JUAN | |
| | Examiner | Art Unit | |
| | Jegatheesan Seharaseyon | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### 1. *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 3*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

II. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 4*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

III. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 5*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

IV. Claims **2-13** and **16-20**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 6*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

V. Claims **2-13** and **16-20**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 7*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

VI. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 8*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

VII. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 9*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

VIII. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 10*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

IX. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 11*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

X. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 12*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

XI. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 13*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

XII. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 14*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

XIII. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 15*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

XIV. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 16*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

XV. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 17*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

XVI. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 18*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

XVII. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 19*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

XVIII. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 20*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

XIX. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 21*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

XX. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 22*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

XXI. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 23*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

XXII. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 24*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

XXIII. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 25*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

XXIV. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 26*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

XXV. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 27*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

XXVI. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 28*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

XXVII. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 29*, expression vectors, and recombinant host cells

comprising same, classified in class 435, subclass 325, for example.

XXVIII. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 33*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

XXIX. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 34*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

XXX. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 35*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

XXXI. Claims **2-13**, drawn to an isolated nucleic acid sequence consisting of *SEQ ID NO: 36*, expression vectors, and recombinant host cells comprising same, classified in class 435, subclass 325, for example.

XXXII. Claims **14, 15, 22** and **23**, drawn to a method for identifying candidate compounds for treating or preventing autoimmune disorders or cancer comprising contacting a recombinant cell with a test compound, classified in class 435, subclass 7.1, for example.

XXXIII. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 3*, classified in class 435, subclass 6, for example.

XXXIV. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 4*, classified in class 435, subclass 6, for example.

XXXV. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 5*, classified in class 435, subclass 6, for example.

XXXVI. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 6*, classified in class 435, subclass 6, for example.

XXXVII. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 7*, classified in class 435, subclass 6, for example.

XXXVIII. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic

acid sequences utilizing *SEQ ID NO: 8*, classified in class 435, subclass 6, for example.

XXXIX. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 9*, classified in class 435, subclass 6, for example.

XXXX. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 10*, classified in class 435, subclass 6, for example.

XXXXI. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 11*, classified in class 435, subclass 6, for example.

XXXXII. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 12*, classified in class 435, subclass 6, for example.

XXXXIII. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 13*, classified in class 435, subclass 6, for example.

XXXXIV. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 14*, classified in class 435, subclass 6, for example.

XXXXV. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 15*, classified in class 435, subclass 6, for example.

XXXXVI. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 16*, classified in class 435, subclass 6, for example.

XXXXVII. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 17*, classified in class 435, subclass 6, for example.

XXXXVIII. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 18*, classified in class 435, subclass 6, for example.

XXXXIX. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic

acid sequences utilizing *SEQ ID NO: 19*, classified in class 435, subclass 6, for example.

LI. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 20*, classified in class 435, subclass 6, for example.

LII. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 21*, classified in class 435, subclass 6, for example.

LIII. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 22*, classified in class 435, subclass 6, for example.

LIV. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 23*, classified in class 435, subclass 6, for example.

LV. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 24*, classified in class 435, subclass 6, for example.

LVI. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 25*, classified in class 435, subclass 6, for example.

LVII. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 26*, classified in class 435, subclass 6, for example.

LVIII. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 27*, classified in class 435, subclass 6, for example.

LIX. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 28*, classified in class 435, subclass 6, for example.

LX. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 29*, classified in class 435, subclass 6, for example.

LXI. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic

acid sequences utilizing *SEQ ID NO: 33*, classified in class 435, subclass 6, for example.

LXII. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 34*, classified in class 435, subclass 6, for example.

LXIII. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 35*, classified in class 435, subclass 6, for example.

LXIV. Claim **21**, drawn to a method for identifying candidate tumor necrosis factor inducible promoters comprising shuffling nucleic acid sequences utilizing *SEQ ID NO: 36*, classified in class 435, subclass 6, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Claim **1** link(s) inventions I-XXXI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims **2-13**. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or

including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Claim **21** link(s) inventions XXXIII-LXIV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim **21**. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

5. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to <u>different</u> products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: Inventions I-XXXI are

directed to sequences that are distinct both physically and functionally, and are not required one for the other. Each sequence requires a separate search of the literature and sequence databases. A search and examination of an Invention as it pertains to all sequences would therefore present the examiner with an undue search burden.

6. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions XXXII and XXXIII-LXIV are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention XXXII requires search and consideration of contacting a recombinant cell with a test compound, which is not required by any of the other Inventions. Each of Inventions XXXIII-LXIV requires search and consideration of shuffling a nucleic acid, which is not required by Invention XXXII.

7. Furthermore Inventions XXXIII-LXIV are directed to sequences that are distinct both physically and functionally, and are not required one for the other. Each sequence requires a separate search of the literature and sequence databases. A search and examination of an Invention as it pertains to all sequences would therefore present the examiner with an undue search burden.

8. Each of Inventions I-XXXI and XXXII are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially

different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids, vectors, and host cells of each of Inventions I-XXXI can be used in materially different method such as gene and cell transplantation therapy.

9. Each of Inventions I-XXXI and each of Inventions XXXIII-LXIV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids, vectors, and host cells of each of Inventions I-XXXI can be used in materially different method such as gene and cell transplantation therapy.

10. The Examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn method claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

11. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method claims will be withdrawn, and the rejoined method

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and method claims may be maintained. Withdrawn method claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method claims should be amended during prosecution either to maintain dependency on the method claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

12. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

14. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

**Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS 10/04

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